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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/621,803 | 07/17/2003 | Kenneth A. Browne | GP131-03.UT | 5941 |

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| EXAMINER | |
|---|---|
| STRZELECKA, TERESA E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | |

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/621,803 | BROWNE, KENNETH A. | |
| | Examiner | Art Unit | |
| | Teresa E. Strzelecka | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



5.00

## DETAILED ACTION

1. This case has been transferred to examiner Teresa Strzelecka because examiner Nicholas Panaro left the USPTO.

2. This office action is in response to an amendment filed April 29, 2005. Claims 1-31 were previously pending, with claims 10-18 and 20-31 withdrawn from consideration. Applicant cancelled claims 10-18 and 20-31, amended claims 1, 3-7 and 9. Claims 1-9 and 19 are pending and will be examined.

3. Applicant's amendements overcame the following rejections: rejection of claims 1-7 and 9 under 35 U.S.C. 102(b) as anticipated by Keller et al.; rejection of claims 1 and 19 under 35 U.S.C. 102(b) as anticipated by Hu et al.; rejection of claims 1 and 8 under 35 U.S.C. 102(b) as anticipated by Liu et al.

4. Applicant's arguments regarding the rejections are moot in view of new grounds for rejection.

### *Claim Interpretation*

5. Applicant did not define the term "immobilized substantially uniformly over a surface", therefore any form of immobilization is considered to result in "substantially uniform" immobilization of nucleic acids over the surface.

6. Applicant did not define the term "within the field of immobilized primers", therefore, any spatial relationship between the immobilized probes and primers is considered to satisfy this limitation.

7. Applicant did not define the term "self-reporting probes", therefore any labeled probe is considered to be "self-reporting".

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan et al. (WO 01/27327; cited in the IDS), as evidenced by Mueller et al. (Histochem. Cell Biol., vol. 108, pp. 431-437, 1997).

Regarding claim 1, Brennan et al. teach a device for amplifying nucleic acids, the device comprising:

a solid support having a surface (Brennan et al. teach a solid support comprising a surface (page 4, lines 28-32; page 15, lines 16-20).);

at least one species of oligonucleotide primer immobilized substantially uniformly over said surface, thereby defining a field of immobilized primers, said at least one species of oligonucleotide primer comprising a sequence complementary to a first strand of said target nucleic acid (Brennan et al. teach at least one species of oligonucleotide primer immobilized onto the surface, each of the primer species complementary to each target nucleic acid (page 7, lines 7-14; page 10, lines 23-29).); and

a plurality of samples of labeled hybridization probes immobilized in an array to the solid support within said field of immobilized primers (Brennan et al. teach a plurality of probes with sequences the same as or complementary to each target nucleic acid immobilized on the same solid support as the primers (page 7, lines 15-17; page 10, lines 30-33; page 11, lines 1-3). Brennan et al.

teach molecular beacon probes which are fluorescently labeled (page 40, lines 32, 33; page 41, lines 1, 2).),

at least one of the labeled hybridization probes immobilized in said array comprising a sequence complementary to an amplicon synthesized using a primer from said field of immobilized primers and said target nucleic acid as a template in a nucleic acid amplification reaction (Brennan et al. teach capturing of the amplicons synthesized by the immobilized primers using the immobilized capture probes (page 8, lines 27-29; page 9, lines 13, 14; page 10, lines 15, 16). Brennan et al. teach probes and primers immobilized within the same areas (page 38, lines 5-9), therefore they teach probes immobilized within a field of immobilized primers.)

each of said plurality of samples of labeled hybridization probes in said array being spatially separated from the others, but not spatially separated from said field of immobilized primers (Brennan et al. teach different probe types spatially separated from each other by immobilization on different areas of the solid support, and immobilized on the same support as the primers (page 10, lines 23-33; page 11, lines 1-3). Brennan et al. teach probes and primers immobilized within the same areas (page 38, lines 5-9), therefore they teach probes immobilized within a field of immobilized primers.), and

each of said plurality of samples of labeled hybridization probes comprising a detectable label prior to contacting said device with any nucleotide polymerizing enzyme (Brennan et al. teach molecular beacon probes which are fluorescently labeled before an array is contacted with a polymerizing enzyme (page 40, lines 32, 33; page 41, lines 1, 2).).

Regarding claim 2, Brennan et al. teach solid supports made of glass or plastic (page 4, lines 28-30).

Regarding claims 3-5, Brennan et al. teach primers and probes covalently immobilized on the support (page 4, lines 32-34; page 18, lines 2-4).

Regarding claim 6, Brennan et al. teach a reverse primer for the target nucleic acid released from the support, i.e., being soluble (page 6, lines 26-33; page 7, lines 1-3; page 8, lines 1-10).

Regarding claims 7 and 8, Brennan et al. teach molecular beacon probes labeled with fluorophores (page 40, lines 32, 33; page 41, lines 1, 2), therefore they teach self-reporting probes.

Regarding claim 9, Brennan et al. do not specifically teach primers comprising a promoter sequence for RNA polymerase, however, they do teach that one of the amplification reactions which can be performed on the primer array is the self-sustained sequence replication (3SR) and cite Mueler et al. reference. As evidenced by Muller et al., 3SR involves using primers comprising T7 RNA polymerase promoter (Fig. 1), therefore, by teaching 3SR Brennan et al. teach primers comprising RNA polymerase promoters.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan et al. (WO 01/27327; cited in the IDS), Hu et al. (WO 01/48242; cited in the IDS) and Stratagene Catalog (p. 39, 1988).

A) Regarding claim 19, Brennan et al. teach the device of claim 1, soluble nucleic acid primers and a control nucleic acid (page 43, lines 31-33), but do not teach kits comprising these elements.

B) Hu et al. teach a kit for nucleic acid amplification on a solid support, the kit comprising a solid support with primers affixed to the solid support and solution phase primers (page 27, 28, [0090]).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have packaged the device of Brennan et al. into a kit form, as suggested by Hu et al. as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantitites of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantitites you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

12. No claims are allowed.

***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS
June 28, 2005

JEFFREY FREDMAN
PRIMARY EXAMINER
6/30/05